REMARKS

Claims pending herein are directed to methods that include determining the presence or absence of a polymorphic variation associated with melanoma in a specific region of the human genome. The claims specify the polymorphic variantion is in an intron of a region between about the position of rs1267618 and about the position of rs1639679 of the human genome.

Applicant files herewith a declaration by Dr. Charles Cantor under 37 C.F.R. 1.132 (the "Cantor Declaration"). In response to the Office's outstanding rejection of claims under 35 U.S.C. 112, first paragraph, the Cantor Decarlation shows the named inventors had possession of the claimed subject matter at the time the above-identified patent application was filed, and that the specification enables the pending claims.

The Cantor Declaration describes methodolgy performed by the named inventors that resulted in the claimed subject matter. The Cantor Declaration concludes the named inventors determined the region claimed was significantly associated with melanoma by (i) identifying a locus containing an incident polymorphic marker associated with the disease in a genome-wide scan, and (ii) verifying multiple polymorphic sites proximal to the incident marker in the locus also were associated with the disease (Cantor Declaration, paragraph 3).

The Cantor Declaration also shows the methodology and results obtained by the named inventors are supported by accepted genetic principles (Cantor Declaration, paragraph 4). In particular, the declaration states the named inventors identified the claimed region as being associated with melanoma when they verified multiple polymorphic variants in the region were significantly associated with the disease.

The Cantor Declaration shows that other research groups using similar methodology have successfully identified another disease-associated region in the human genome (Cantor Declaration, paragraph 5). Accordingly, the methodolgy has been independently and successfully utilized after the filing date of the patent application herein to identify disease associated regions.

That the named inventors identified the disease-associated region claimed by analyzing a representative number of polymorphisms also is described in the Cantor Declaration. Paragraph 6 of the Cantor Declaration shows that the named inventors analyzed 23% of the polymorphisms currently in the HapMap database having a minor allele frequency of greater than 0.05 in the claimed region. This analysis compares the number of polymorphisms in the claimed region presently in the HapMap database to the number of polymorphisms described in the patent application more than three-and-a-half years ago, and therefore, the degree of overlap described in the Cantor Declaration likely is underestimated. The Cantor Declaration also states this degree of overlap is on par with, or better than, the degree of overlap others had when making disease associations after the above-identified patent application was filed.

In paragraph 7, the Cantor Declaration outlines experimental evidence in the specification of the above-identified patent application that supports the named inventors' determination the claimed region was associated with melanoma. Specifically, haplotype analysis in the specification provided further support that the claimed region was associated with melanoma, as addressed previously in the amendment and response filed on May 28, 2007.

The Office stated in an interview summary for another patent application (application no. 10/723,518) that guidance in that specification did not allow the skilled artisan to determine which of the polymorphisms, identified after the invention was filed, were and were not associated with the disease and that trial and error experimentation would be required to identify which of the additional polymrphisms were disease-associated. The Cantor Declaration shows this rationale is not applicable to the subject matter claimed herein. The claimed processes include determining the presence or absence of a polymorphic variation associated with melanoma in the specified region. The Cantor Declaration shows the named inventors identified this specified region as associated with melanoma, and provided a representative number of polymorphic variations associated with melanoma in the specification. The identification of this "hot zone" allows for the possibility of the person of ordinary

skill in the art to determine whether there might be any polymorphic variations associated with melanoma in the region other than those described in the specification. Because the specification describes a number of methods for typing polymorphic variants known in the art at the time of filing, this determination would be routine. Thus, the specification meets the requirements for enablement and written description under 35 U.S.C. 112, first paragraph.

Accordingly, the specification enables and provides a written description of the claimed subject matter. Applicant therefore respectfully requests withdrawal of the rejections under 35 U.S.C. 112, first paragraph.

CONCLUSIONS

Applicant respectfully submits all pending claims will be in condition for allowance upon entry of the amendments herein. Applicant respectfully solicits a prompt notification to this effect, and the Examiner is encouraged to contact the undersigned representative (contact information below) to promptly resolve any remaining issues or questions.

In the unlikely event a fee calculation document or other pertinent document is separated from this submission and the Office determines that an extension and/or other relief is required, Applicant petitions for any required relief, including extensions of time, and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. **50-3473**.

Respectfully submitted,

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